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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/661,259

09/12/2003

Ben-Zon Dolitzky

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EXAMINER

CHANG, CELIA C

ART UNIT

PAPER NUMBER

1625

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/661,259	Applicant(s) DOLITZKY ET AL.	
	Examiner Celia Chang	Art Unit 1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 November 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10, 121 and 123-130 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10, 121 and 123-130 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
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| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Amendment and response filed by applicants dated Nov. 21, 2007 have been entered and considered carefully.

Claims 11-120, 122, 131 have been canceled. Claims 1-10, 121 and 123-130 are pending.

2. The rejection of claim 1 and 3 under 35 USC 112 first paragraph for using "negligible" amount of solvent is maintained for reason of record.

If the product is produced using a two layer system, then, both layers cannot be negligible. Negligible amount can be the residue amount of solvents after drying which can be "warrant little or no attention". As long as substantial amount has to be added to make a two layer system, the amount cannot be "warrant little or no attention" because certain quantity must be introduced with the intention of making two layers.

3. The rejection of claims 6-9 over Kumar et al. '124 in view of Hackh's, Liberman, Sekiguchi or Leucuta is maintained for reason of record.

The gist of applicants argument is that Kumar et al. '124 already produced a powder of fexofenadine hydrochloride which would not motivate one skilled in the art to further modify such powder.

The Liberman reference pages 107-112 is hereby provided for applicants' convenience. While in the same book about reducing particle size by milling as recited in the previous office action, it clearly stated that size reduction is always desirable since it promotes bioavailability. However, fine powder may result in undesirable effects in process (see p.112). Therefore, one skilled in the formulation art is well aware of such size reduction must be done under "optimum" sizing as to give the best bioavailability as well as processing quality. Therefore, given the Kumar reference and motivated by the state of the art for size reduction to an optimum, one having ordinary skill is given the technology and suggestion to add a triturating step for better size reduction.

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4. The rejection of claims 1-10, 121, 123-130 under 35 U.S.C. 103(a) as being unpatentable over Kumar et al. WO 00/71124 in view of Hackh's Liberman, Sekiguchi or Leucuta, further in view of Okabe et al. CA 114:54120 or Williams et al. US 6,862,890; or

the rejection of claims 1-10, 121-131 under 35 U.S.C. 103(a) as being unpatentable over Carr et al. US 4,254,129, 4,285,957, or WO 95/31437 (all cited on 1449) or Woosley US 5,375,693 in view of Lieberman, Suzuki et al. CA 91:44479, Corrigan et al. CA 98:166814, Nuernberg CA 86:8603 and Sato CA 110:179429 supplemented with US 5,990,127, are maintained for reason of record.

The gist of applicants' arguments with respect to the 103(a) rejections relied upon that there are other steps in the claim, therefore, the sole difference between the claims and the prior art is not spray drying vs evaporation.

Please note that the other steps in claim 1 is "preparing a solution, removing a portion of the solvent, adding another solvent, when two layer forms, separate the two layers". This adding one solvent, adding another immiscible solvent so that two layer forms to separate the lower layer is clearly known conventionally in the chemical art as "extraction" process. Please note that whether the fexofenadine hydrochloride was dissolved in one solvent or extracted into another solvent, such steps are the preparation step of solution making conventional in the chemical art. The Kumar '124 reference on pages 4-5 delineated preparation of solution. The Williams '890 reference taught that spray drying is solvent removal procedure analogous to other conventional solvent removing procedures (see col. 1, lines 26-27, col. 2 lines 59-60) and particularly taught the equivalency between applicants tetrahydrofuran and other alcohols such as those used by Kumar '124. Okabe et al. is further evidence that such analogue between spray drying and evaporation is a broad spectrum approach per ponderously conventional in the industry in amorphous solid preparation. Attorney's attempt to show unobviousness by comparing only the difference of *each individual* reference instead of the combination of well-known analogous art in the field does not warrant any probative value. In re Merck & Co. 231 USPQ 375, Ex parte GPAC Inc. 29 USPQ2d 1406. Please note both Kumar and Williams have particularly "named" applicants compound and the all three references are for "solid amorphous" product procedure, thus, all are analogous art. Although the Okabe reference was recited as an example of the well known nature between spray drying and *rotary* drying, per ponderous of

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evidence in the pharmaceutical art support the analogue, see for example CA 139:219273, CA 113:120830, CA 138:390718, CA 141:179642, (all references provided in action dated 9/8/2006) which are just a brief browsing of the most recent publication.

Further, on page 9 of the specification, it has clearly disclosed that trituration is an optional step further made “after” an amorphous form was received. The art is well documented that changing solvents, using spray dry or other drying are well described technique for obtaining amorphous. Applicants provided mere argument without factual support that the mere picking and choosing of the fast available technique would make any difference in obtaining an amorphous product with any advantage.

4. The rejection of claims 1-10, 121 and 123-130 under 35 USC 102(e) or (g) is maintained for reason of record.

The examiner apologize for naming Switzerland a NAFTA country while it is a GATT country (see Ladas & Parry). Priority date for US2005/0165056 which has a filing date PCT/CH02/00027 of Jan. 17, 2002. The instant application has a filing date PCT/US02/11251 of Apr. 8, 2002. Therefore, irrespective of the priority benefit, the filing date of pregrant US2005/0165056 is a *provisional* 102(e) reference.

However, if the priority benefit is compared, the Gatt country would be entitled to the priority benefit (see Storwick or Voight) when considering the 102(g) issues. Therefore, the rejection would be proper.

Applicants again argued that “preparing a solution, removing a portion of the solvent, adding another solvent, when two layer forms, separate the two layers” was not claimed therefore cannot be considered. This adding one solvent, adding another immiscible solvent so that two layer forms to separate the lower layer is clearly known conventionally in the chemical art as “extraction” process. Please note that whether the fexofenadine hydrochloride was dissolved in one solvent or extracted into another solvent, such steps are the preparation step of solution making conventional in the chemical art whether explicitly claimed or not.

Mere argument cannot support that describing the extraction process by each step is different from describing the extraction process by using the term "extraction and separation". No factual evidence provided that the steps describing the extracting process actual produced

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products which have any property that is different from any other amorphous anhydrous fexofenadine hydrochloride.

5. THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celia Chang, Ph. D. whose telephone number is 571-272-0679. The examiner can normally be reached on Monday through Thursday from 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet L. Andres, Ph. D., can be reached on 571-272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

OACS/Chang
Feb. 28, 2008

/Celia Chang/
Primary Examiner
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